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DATE MAILED: 09/28/2006

CONFIRMATION NO. ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR 380804.00116 6851 Glenn H. MacKal 10/681,580 10/06/2003 EXAMINER 7590 09/28/2006 Stefan V. Stein KEASEL, ERIC S Holland & Knight LLP PAPER NUMBER ART UNIT **Suite 4100** 100 N. Tampa Street 3753 Tampa, FL 33602-3644

Please find below and/or attached an Office communication concerning this application or proceeding.

	A II - Al N	
Office Action Summary	Application No.	Applicant(s)
	10/681,580	MACKAL ET AL.
	Examiner	Art Unit
	Eric Keasel	3753
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1)⊠ Responsive to communication(s) filed on <u>26 June 2006</u> .		
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 1-3,5,6 and 9 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-3,5,6 and 9</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10)⊠ The drawing(s) filed on <u>March 3, 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attach mont/o)		
Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)		
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	nte
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	5) Notice of Informal P 6) Other:	аселс Арріісасіол

### **DETAILED ACTION**

1. In view of the supplemental appeal brief filed on June 26, 2006, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

SUPERVISORY PATERY EXAMINER

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# Claim Objections

2. Claims 2, 3, 5, 6, and 9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It does not appear that applicant has positively recited the pill (note the claim construction "for receiving a dissolvable pill"). If it is applicant's contention that the pill is not positively recited, then the dependent claims do not further limit the scope of claim 1. If applicant intends to positively recite the pill, then applicant should change "for receiving" to --and-- in claim 1.

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 1-3, 5, 6, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 appears to recite only a body with an intended use recitation, "for a dissolvable pill". However, the rest of claim 1 and dependent claims appear to recite additional features of the pill. It is unclear if the pill is meant to be positively recited or not. Claim 9 further complicates matters by appearing to positively recite "an annular pill". It is unclear if this is meant to be the same pill recited in claim 1 or if this is meant to be the first (and only) positive recitation to a pill in the claims.

The claims are incomplete for omitting essential elements, such omission amounting to a gap between the elements. The claims appear to be directed to an automatic inflator, but the only structure recited is a body and (perhaps) a pill. This does not define an automatic inflator.

Sufficient structure (e.g. the gas source, the item that is inflated, etc.) should be recited to define a complete invention.

In light of the above informalities, the claims have been examined as could best be understood by the examiner. The examiner's failure to apply prior art to any of the claims should not be construed as an indication of allowable subject matter.

## Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1-3, 5, 6, and 9 (as understood) are rejected under 35 U.S.C. 102(b) as being anticipated by Hooberman (US Patent Number 5,592,962).

In Fig. 1A, Hooberman teaches of an automatic inflator comprising a body (24, 32) for receiving a dissolvable annular pill (28, 30) including an upper surface (annular surface facing) and a lower surface (annular surface axially opposed), the upper surface having a radially extending undulating configuration (note radially concentrically castellated inner portion) according to the claims. The castellated inner portion has peaks and troughs. As seen in figure 1A, the castellated inner portion extends through the pill to the proximal surface and are

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therefore is on both surfaces of the pill. Although particular structures of Hooberman's pill corresponding to the claim limitations have been pointed out for arguments sake, the pill itself is not actually being claimed. As per claim 1 the claim is directed to an automatic inflator comprising a body *for* receiving a dissolvable pill [emphasis added] and not to the combination of an inflator and pill. The inflator of Hooberman is capable of accommodating such a pill and therefor meets the claims. Further, even if the pill were to be positively recited in combination with the inflator, the applicant has failed to identify any criticality of the undulations being in or out of phase and the limitation would therefor fail to patentably define over the prior art.

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7. Claims 1-3, 5, 6, and 9 (as understood) are rejected under 35 U.S.C. 102(b) as being anticipated by Bernhardt et al. (US Patent Number 3,526,339).

Bernhardt et al. disclose an automatic inflator comprising a body (1) for receiving a dissolvable annular pill (26) including an upper surface and a lower surface both with an undulating (i.e. wavy or curved) configuration according to the claims. Although particular structures of the pill of Bernhardt et al. corresponding to the claim limitations have been pointed out for arguments sake, the pill itself is not actually being claimed. As per claim 1 the claim is directed to an automatic inflator comprising a body *for* receiving a dissolvable pill [emphasis added] and not to the combination of an inflator and pill. The inflator of Bernhardt et al. is capable of accommodating such a pill and therefor meets the claims. Further, even if the pill were to be positively recited in combination with the inflator, the applicant has failed to identify any criticality of the undulations being in or out of phase or the pill having a center hole, so the limitations would therefor fail to patentably define over the prior art.

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8. Claims 1-3, 5, 6, and 9 (as understood) are rejected under 35 U.S.C. 102(b) as being anticipated by Licher (US Patent Number 3,308,494).

Licher discloses an automatic inflator comprising a body (see Fig. 3) for receiving a dissolvable annular pill (53, 163, 164, and other ref. nos. in other embodiments) including an upper surface and a lower surface with an undulating configuration according to the claims.

Note also, the serrations and apertures in various embodiments. Although particular structures of the pill of Licher corresponding to the claim limitations have been pointed out for arguments sake, the pill itself is not actually being claimed. As per claim 1 the claim is directed to an automatic inflator comprising a body *for* receiving a dissolvable pill [emphasis added] and not to the combination of an inflator and pill. The inflator of Licher is capable of accommodating such a pill and therefor meets the claims. Further, even if the pill were to be positively recited in combination with the inflator, the applicant has failed to identify any criticality of the undulations being in or out of phase, so the limitation would therefor fail to patentably define over the prior art.

# Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-3, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooberman in view of Licher.

It would appear that Hooberman discloses all the positively recited features.

Alternatively, if the shapes set forth in the claims are not met by Hooberman, then the claims are rejected as follows. Licher discloses a similar inflator with a dissolvable pill. Licher also recognizes that the shape of the dissolvable pill is a results effective variable, i.e. a variable that achieve a recognized result. In the instant case, the shape is chosen to have a greater surface area so that the pill dissolves quickly (see column 3, lines 29-43). Since the prior art recognizes the shape as a results-effective variable, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have chosen the shapes set forth in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (see MPEP 2144.05).

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11. Claims 1-3, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernhardt et al. in view of Licher.

It would appear that Bernhardt et al. disclose all the positively recited features.

Alternatively, if the shapes set forth in the claims are not met by Bernhardt et al., then the claims are rejected as follows. Licher discloses a similar inflator with a dissolvable pill. Licher also recognizes that the shape of the dissolvable pill is a results effective variable, i.e. a variable that achieve a recognized result. In the instant case, the shape is chosen to have a greater surface area so that the pill dissolves quickly (see column 3, lines 29-43). Since the prior art recognizes the shape as a results-effective variable, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have chosen the shapes set forth in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (see MPEP 2144.05).

12. Claims 1-3, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Licher.

It would appear that Licher discloses all the positively recited features. Alternatively, if the shapes set forth in the claims are not met by Licher, then the claims are rejected as follows. Licher also recognizes that the shape of the dissolvable pill is a results effective variable, i.e. a variable that achieve a recognized result. In the instant case, the shape is chosen to have a greater surface area so that the pill dissolves quickly (see column 3, lines 29-43). Since the prior art recognizes the shape as a results-effective variable, it would have been obvious to one having

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ordinary skill in the art at the time the invention was made to have chosen the shapes set forth in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (see MPEP 2144.05).

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## **Double Patenting**

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1, 2, and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,705,488. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of '488 anticipates claims 1, 2, and 9 of the present application.

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#### Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ivie, Spidy, and Novak disclose similar devices.

16. Any inquiry concerning this communication should be directed to Eric Keasel at telephone number (571) 272-4929, who can normally be reached Monday-Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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